time for Clear Creek County to sell certain lands that it received from the United States under legislation passed in 1993.

Under that legislation—the Clear Creek County, Colorado, Public Lands Transfer Act—the County took title to certain public lands with explicit authority for their sale, subject to two basic requirements: the County must pay to the United States any net proceeds realized after deduction of allowable costs, as defined through agreement with the Secretary of the Interior; and any lands not sold within 10 years after enactment of the Transfer Act must be retained by the County.

In the last Congress, I introduced a bill to extend for an additional ten years the period during which the County will be authorized to sell these lands. This has been requested by the Commissioners of Clear Creek County because it has taken longer than anticipated for the county to implement this part of the Transfer Act. Additional time would mean a greater likelihood that the County can sell these lands, and thus a greater chance that the national taxpayers will benefit from payments by the County. Last year, the House passed the time-extension bill, but the Senate did not complete action on it.

The bill I am introducing today is almost identical to the one the House passed last year. The only difference is that the new bill would extend until May 19, 2015 the time for the county to sell the lands in question—one year longer than under the previous bill. The additional year would be provided in recognition of the additional time that will now be required for the bill to be enacted into law.

TMJ IMPLANTS

HON. THOMAS G. TANCREDO

OF COLORADO

IN THE HOUSE OF REPRESENTATIVES

Wednesday, January 3, 2001

Mr. TANCREDO. Mr. Speaker, in April 1999, I received a phone call and correspondence from TMJ Implants, a company located in Golden, Colorado, in my district, which had been having problems with the review of its Premarket Approval Application of the TMJ Total and Fossa-Eminence Prosthesis by the United States Food and Drug Administration (FDA). Over the last year and a half—and delay after delay resulting in the pulling of the implants from the market, I have watched the process drag on, leading to the loss of millions of dollars by the company and countless number of patients who have been put through unnecessary pain. While I will let my submission speak for itself, suffice it to say that I sincerely believe that most of the frustration could have been avoided had everyone sat down and laid everything out on the table in the spirit of what was called for under the FDA Modernization Act. Unfortunately, the agency has been unwilling to do so—and it seems that these problems will continue into the foreseeable future.

Over the last year and a half, my office has received numerous letters from physicians all across the country—from the Mayo Clinic to the University of Maryland—each relaying to me the benefit of the partial joint and the fact that the partial and total joint results in immediate and dramatic decrease in pain, an increase in range of motion and increased function. To date, there is no scientific reasoning for the fact that the total and partial joints are not on the market. All of this calls into question the integrity of the agency—something that I find very disturbing.

Dr. Christensen is a true professional and a pioneer in his field and holder of the first patents. His implants are widely accepted as effective and safe throughout the dental and surgery community—indeed, several of my constituents have literally had their lives changed by the procedure.

I am convinced that the work of TMJ is based on solid, scientific principles and the removal of the implants from the market has been and continues to be erroneous, contrary to the Agency's earlier findings and the statutory standard that should be applied.

I would like to take this opportunity to submit into the RECORD a copy of a letter from Mr. Roland Jankelson to the FDA urging the agency to come to an agreement as soon as possible so that this disaster is remedied and thousands of patients in the general public can receive relief.

ROLAND JANKELSON,
15 PONCE DE LEON TERRACE,
Tacoma, WA, December 28, 2000.

MR. LES WEINSTEIN,
U.S. Food and Drug Administration, Ombudsman, Center for Devices and Radiological Health,
9200 Corporate Blvd., Rockville MD.

Re: TMJ Implants, Inc.

DEAR MR. WEINSTEIN,

With reference to our phone conversation today, please note the following comments (especially the last point, which I hope will shape your actions in the next couple of days):

1. There is no need for another meeting with ODE. The purposes of this meeting (as stated in the Blackwell E-mail) are bogus—just more obfuscation and more delay. As Mike Cole stated in his December 27, 2000 letter to Tim Ulatowski, a copy of which you have: ''You say we must arrive at an acceptable, consistent diagnosis criteria in order to write a label''. I say we are already there, and have been for two months . . . (Underlining is my emphasis).

2. There never has been any credible evidence before the FDA of a safety problem (in over thirty plus years of use) that would prevent the Christensen devices (total and partial joint) from meeting the required standard of reasonable assurance of safety. Approval was given to TMJ Concepts device with limited data and little history. The information, data and history given to FDA for the TMJ Implants device exceeds many-fold, by every possible measure, the composite of information used to approve its competitor. The Christensen Company, its consultants and its attorneys have responded to every issue, every hypothetical concern posed by FDA, no matter how far-fetched these issues and concerns were. See Mike Cole's notes attached for just a quick summary of the Company's responses since the October Panel meeting. As Mr. Cole states in his letter, the questions posed in the Blackwell E-mail were addressed two months ago. Yet, for two months, there has been no response from the Ulatowski side. You and Mr. Ulatowski have been informed that this was a company on the verge of financial ruin. This does not make any difference to Mr. Ulatowski—It is not his concern, not his focus. A man's reputation, ruined. A company financially gutted. Patients suffering. ''Myotronics'' all over again. How could this happen again? it has.

With respect to the meeting called for in the Blackwell E-mail: There is no more explanation needed from the Company. There is no more ''perspective (Blackwell's word) to share. Just more delay.

3. Forget that Dr. Christensen faces financial ruin. Forget that his company's resources are nearly exhausted. Every day that goes by without FDA approval of the TMJ Implants, Inc. total joint, and partial joint in particular, is a day that patients suffer. The PMA record is indisputable. Physicians and patients have uniformly made it clear that the FDA is harming them. The FDA is on notice that physicians are withholding needed surgery, waiting for the Christensen devices, both total and partial joint. The physicians have uniformly made it clear to the FDA that the TMJ Concepts, Inc. joint is unacceptable for their patients. Others have made it clear that without the availability of a partial joint, patients will be subjected to surgery that unnecessarily destroys healthy anatomy. Witholding approval of these devices is a willful disregard by FDA of the public health. Ulatowski does not care.

4. About five years ago, Rick Blumberg, Deputy Counsel for Litigation, for whom I have great respect, persuaded me to forego what would have extended FDA's involvement in the Myotronics matter, i.e. litigation by Myotronics that would have further publicized the already well-publicized findings of more than two years of Congressional hearings, OIA and IGHHS investigations. Rick assured me, and I believe he believed, that the FDA was, indeed, changed in reaction to the revelations of the multiple and extra-legal activities of FDA employees intentionally directed at and intended to harm Myotronics. BUT HE WAS WRONG! The abuse, misuse of agency authority for the pursuit of a private agenda to harm a targeted company, retaliation and punishment, is all repeated against TMJ Implants, Inc., whose devices for thirty plus years served a specialized ''salvage need'' and relieved human suffering. Standing in the middle of these abuses: the same Mr. Tim Ulatowski.

5. The record cries out for intervention by you and other responsible FDA officials. Neither Susan Runner nor Tim Ulatowski have credibility in this matter. In reviewing this matter, you and senior FDA and OIA officials should look at a number of issues:

(a) A phone call from Dr. Susan Runner to Dr. Christensen days before the May 1999 Panel meeting informing Dr. Christensen that his PMA would be disapproved, and advising him to withdraw it.

(b) Information leaked by the FDA prior to the 1999 Panel that TMJ Implants, Inc. devices ''were either withdrawn by FDA or would soon be''. Remember the FDA leaking in the Myotronics case.

(c) Treatment of TMJ Implants, Inc. PMA's with standards different than used for its competitor, TMJ Concepts, Inc.'s PMA: TMJ Concepts, Inc. was approved without delay in spite of a device history covering only a few years and limited data, compared to a device history of more that thirty years for the Christensen devices, and much more data.

(d) Removal of the partial and total joint form the market in spite of a 9–0 Panel approval and a need acknowledged the FDA Panel.

(e) Allegations that Dr. Susan Runner had a conflict of interest stemming from her past relationship with Dr. Mecuri, TMJ Concepts, Inc. chief technical consultant—allegations rejected by OIA without any apparent serious injury.

(f) Data and evidence covering over thirty years of use that demonstrates a remarkable safety record. Why has this device been held hostage?

(g) Staff's dismissal of TMJ Implants, Inc. request for the addition of qualified experts for the October 2000 Panel.

(h) The assembly of a Panel for the October 2000 meeting which lacked balance and qualifications. Only one certified Oral Maxillo-Facial surgeon among five consultants. Why?

(i) Concerns about the independence of a number of October 2000 Panel members and consultants.

(j) Acknowledgement by one of the October 2000 Panel members to Dr. Christensen *prior to the Panel meeting* that he believed (knew) the Panel would recommend disapproval.

(k) Acknowledgement by the same Panel member that he knew by the noon break in the October 2000 Panel meeting that members intended to vote for disapproval.

(l) Acknowledgement by the same Panel member that he believed the PMA (the TMJ Implant, Inc. partial joint) should be approved, but that he voted for disapproval (with the majority) because he believed he would not otherwise be invited to another panel. So much for the idea of independence!

(m) Questions concerning why the partial joint PMA was subjected to a second Panel (the October 2000 Panel) after a May 1999 Panel recommended approval 9–0 (what conditions).

(n) Questions regarding the appropriate level of micro-management of diagnostic protocols, and pathology indications, and why labeling provided by the company was deemed unacceptable. On the issue of concern about improper staff micro-management, see December 31, 2000 letter from Roland Jankelson to Lee Weinstein.

(o) Did the Ulatowski group, particularly Susan Runner, ignore information and misrepresent data and information provided by the Company? Incompetence? Deliberate?

(p) Did the Ulatowski group ignore for two months the Company's responses following the October 2000 Panel meeting when it knew the delay threatened the financial viability of the Company? See (1) Mile Cole notes, and (2) Mike Cole letter to Ulatowski dated December 27, 2000.

(q) Questions about Susan Runner's independence and objectivity. Appearances of a personal agenda to favor TMJ Implants, Inc. competitor. Differences of standards and treatments applied to each are indisputable. Why did it happen?

(r) Concern about the extraordinary delay in the review process, continuing to this date, and whether it is intended to deliberately punish TMJ Implants, Inc. There are similarities between this case, and a history of retaliation by FDA employees revealed by 1995–1996 hearings of the House Subcommittee on Oversight and Investigations.

(s) Concern about Susan Runner's competence (qualifications, training and experience) to review these particular devices.

(t) Questions about why the Ulatowski group has ignored the physicians' claims of patient harm from the removal of these devices from the market. See sample of physicians' letters. See sample of patients' letters.

6. No more meetings, please. No more conference calls that just provide more delay. Have Tim Ulatowski put in writing all matters with which he is not satisfied, any standing in the way of approval. If he cannot state it in writing, ''it should not exist''. Have this happen on Tuesday, Ulatowski's first day back (while he took last week away from work, Dr. Christensen continued to ''bleed'' more money). Get this PMA done next week. We can argue about culpability, need for investigations and legal remedies later. I thank you in advance for doing what needs to be done.

Sincerely,

ROLAND JANKELSON.

SENATE COMMITTEE MEETINGS

Title IV of Senate Resolution 4, agreed to by the Senate on February 4, 1977, calls for establishment of a system for a computerized schedule of all meetings and hearings of Senate committees, subcommittees, joint committees, and committees of conference. This title requires all such committees to notify the Office of the Senate Daily Digest—designated by the Rules committee—of the time, place, and purpose of the meetings, when scheduled, and any cancellations or changes in the meetings as they occur.

As an additional procedure along with the computerization of this information, the Office of the Senate Daily Digest will prepare this information for printing in the Extensions of Remarks section of the CONGRESSIONAL RECORD on Monday and Wednesday of each week.

Meetings scheduled for Thursday, January 4, 2001 may be found in the Daily Digest of today's RECORD.

MEETINGS SCHEDULED

JANUARY 9

10:30 a.m.
Foreign Relations
To hold hearings on a United Nations Reform Report.
SD–419

JANUARY 16

10:30 a.m.
Foreign Relations
To hold hearings on the nomination of Colin L. Powell, to be Secretary of State.
SH–216

JANUARY 17

10:30 a.m.
Foreign Relations
To hold hearings on the nomination of Colin L. Powell, to be Secretary of State.
SH–216